Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2004P-0349
Docket Title: Action on Products containing added Mercury

September 28, 2004

Dear Dockets Manager:

Please include the attached comment letter and supplemental document regarding docket number 2004P-0349 on the FDA's e-docket for public access and review.

Sincerely,
Rita C. Shreffler

Rita Shreffler
Pres Liaison
National Autism Association
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2004P-0349 C3

NATIONAL AUTISM ASSOCIATION

Think Autism. Think Cure.

September 28, 2004

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2004P-0349
Docket Title: Action on Products containing added Mercury

Dear Dockets Manager:

The National Autism Association (NAA) requests the FDA's consideration of the following comments on the above referenced draft guidance.

NAA supports the removal of the mercury-based preservative thimerosal from all vaccines manufactured or distributed in the United States. Along with a growing number of researchers, we believe that exposure to mercury though increased use of thimerosal–containing vaccines in the 1990's has led to a public health crisis surpassing all others in our nation's history in scope and severity. The rise in pediatric neurological disorders consistent with mercury toxicity is in direct proportion to the increase in the amount of mercury our children received through vaccines. We believe this to be the principal reason that an estimated one in six children now requires special education services in this country.

Our organization hears daily from an increasing number of families who are convinced their children's diagnoses such as autism and ADHD are directly attributable to gross overexposure to mercury received through vaccines.

The extreme neurotoxicity of mercury in general and thimerosal in particular has been known for decades. We ask the FDA to consider that in 1935, veterinary vaccine manufacturer Pittman-Moore wrote in a letter to Eli Lilly & Co., the original producer of thimerosal:

"We have obtained marked local reaction in about 50% of the dogs injected with serum containing dilutions of Merthiolate... .Merthiolate is unsatisfactory as a preservative for serum intended for use on dogs."1

In a study published in 1977, D.G. Fagan refers to 10 deaths among 13 infants upon which thimerosal was used as a topical treatment for umbilical hernias and found that:

"in 9 of the 10 cases autopsies revealed organ mercury levels in the liver, kidney, blood and brain. ..thimerosal can induce blood and organ levels of organic mercury which are well in excess of the minimum toxic levels in adults and fetuses."2

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A 1983 study published in a Russian Epidemiology journal states:

" . thimerosal. .has been found not only to render its primary toxic effect, but also capable of changing the properties of cells. This fact suggests that the use of thimerosal for the preservation of medical biological preparations, especially those intended for children, is inadmissible."3

More recently, in the year 2000, FDA scientist William Slikker states in the journal *Neurotoxicolcogy:*

"Thimerosal crosses the blood-brain and placental barriers and results in appreciable mercury content in tissues including brain."4

We have attached a recent letter from former Austrian chief regulator of vaccines and blood products, Dr. Wolfgang Maurer, to governor Arnold Schwarzenegger in support of AB 2943 to ban thimerosal from childhood vaccines in the state of California. Dr. Maurer refers to a 1993 meeting at which FDA officials were further warned of thimerosal's toxicity. This became yet another unheeded wake-up call leading to tragic consequences for the children of our country.

That such a powerful neurotoxin as mercury continues to be injected into humans, especially newborns and infants, is unconscionable. That the amount of mercury injected into the most vulnerable among us was allowed to triple during the 1990's has wreaked havoc on hundreds of thousands of lives. The resulting devastation to the affected families—physically, emotionally, and financially—is incalculable.

The needless exposure to mercury through vaccines must be eliminated before more children are harmed.

Sincerely,

Jo Pike, President
Lori McIlwain, Executive Director
Laura Bono, Board Chairman
Scott Bono, Media Consultant
Wendy Fournier, Secretary
Rita Shreffler, Press Liaison
National Autism Association

References:

1. Director of Biological Services, Pittman-Moore Company, letter to Dr. Jamieson of Eli Lilly Company dated 1935. U.S. Congressional Record, May 21, 2003, E1018, page 9.
2. Fagan DG, Pritchard JS, Clarkson TW, Greenwood MR. "Organ mercury levels in infants with omphaloceles treated with organic mercurial antiseptic." *Archives of Disease in Childhood.* 1977 Dec; 52 (12):962-4.
3. Kravchenko AT, Dzagurov SG, Chervonskaia GP. "Evaluation of the toxic action of prophylactic and therapeutic preparations on cell cultures. III. The detection of toxic properties in medical biological preparations by the degree of cell damage in the L132 continuous cell line." *Zh Mikrobiol Epidemiol Immunobiol.* 1983 Mar;(3): 87-92.
4. Slikker, William, Jr. "Developmental Neurotoxicology of Therapeutics: Survey of Novel Recent Findings." *Neurotoxicology*, 21, page 250 (2000).

MAG.DDR.WOLFGANG MAURER
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16.Sept. 2004

To Governor
Arnold Schwarzenegger
California -USA

per e-mail

Re: Thiomersal in Vaccines and other medicinal products/devices

Dear Mr. Schwarzenegger,

Lieber Herr Schwarzenegger,

Being a regulator of biologicals (vaccines and blood products) and responsible head for the scientific evaluation of this products in Austria from 1988-98 I asked the Austrian Ministry of Health to ban thiomersal in 1988.

My initial concerns were that when introducing new vaccines as the HIB-vaccine and the Hepatitis B vaccine the body burden of thiomersal (mercury) would be beyond international limits.

In addition frequent vaccination with thiomersal containing vaccines would be a nearly ideal way to sensitize up to 20% of the population. Since sensitization against a vaccine ingredient is a contraindication for following immunizations the further use of thiomersal would severely jeopardize all vaccination programs. In Graz- a town you know better than I- sensitization rates against mercury are higher than against nickel. Reason: TBE Vaccination ("Zeckenschutzimpfung).

At the beginning of my regulatory activities I was quite alone with my concerns, but manufacturers were informed about the thiomersal concerns mainly in the time period from 1988-1992. With some pressure Baxter/Vienna (Immuno) organized a thiomersal meeting in 1992 where I could present my concerns to the public. Other manufacturers (GSK, MSD, Aventis, Berna) have been informed during this time. In addition – although not on the agenda- at a WHO workshop at may institute in Dec 1993 I discussed this issue with regulators from FDA, Canada, and WHO (head of biologics). According to the European Pharmakopoiea- one legal basis of vaccines production it is stated (Eur Ph 1998:0153) that *"vaccines are as far as possible free from ingredients known to cause toxic, allergic or other undesirable reactions in man."* So since it is possible to produce a thiomersal free vaccine its use is not permitted according to this monograph.

When Austria became a member of the European Union I suddenly had some colleagues within the regulatory European bodies (Biotech Working party at EMEA and European Pharmokopoiea) who shared my concerns. When I left the regulatory field in 1998 the fundamentals existed to ban thiomersal in July 1999 together with EMEA, FDA and WHO.

As a physician and biochemist I know that the addition of a preservative at least in one-dose containers is not at all necessary. The first preservative free vaccines were produced in the late 60ies (!!!). According to this the US pharmocopoie has-since decades- the wording *"the addition of a preservative must not be a substitute for GMP"*. So when not banning thiomersal we would encourage those parts of the biotech industry which is not up to date with safe filling equipment and clean room technology.

However our children and we have the right for best health with the best vaccines available. And highly developed countries like the US can afford thiomersal free state of the art one-dose vaccines (preferably ready to use syringes). Ongoing use of thiomersal containing vaccines against the concerns of many parents would automatically decrease coverage and loss of trust and would increase the risk of vaccine preventable epidemics.

Due to this facts Austria started to use thiomersal free vaccines whenever available in 2000. And we were happy to have thiomersalfree vaccines for 99% of our babies in 2000 (in part US production). It is now practically 100%. Now there is no manufacturer on the market in Austria with thiomersal containing influenza vaccines. This is a big jump in vaccine quality.

So since nearly 5 years it is not necessary to consider concerns whether wanted or not like "thiomersal causes autismus" because we do not use this preservative any more.

In addition to the elimination of thiomersal from vaccines thiomersal should be eliminated from all medicinal products and also medical devices like contact lenses washing fluids.

Dear Mr. Schwarzenegger in the past I was one of the first scientists who asked to ban thiomersal. I am convinced that this is the right way to protect our children, to be able to further introduce new vaccines and to boost high quality biotech industry.

Mit freundlichen Grüßen

No signature per e-mail

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